

### **REMARKS**

Claims 1, 3-6, 13, 15-18, and 25-42 were previously pending. By this paper all previously pending claims are canceled, and new claims 43-64 are added. Support for the new claims can be found in the application and claims as filed. See, for example, page 28 line 3 and lines 9-16, and page 29 line 19 and lines 28-29 of the application as filed, and original claims 3, 5, and 8, describing methods of treatment of supraventricular tachyarrhythmia. See also, for example, page 28 line 4 and line 31 of the application as filed, and original claim 6, describing the use of JTV-519. See also, for example, page 26 lines 14-24 of the application as filed, describing routes of administration. See also, for example, page 93 lines 18-20 of the application as filed, describing administration of from about 100nM to about 1000nM JTV-519. Accordingly, no new matter is added.

#### **I. Claim Rejections Under 35 U.S.C. §112, 1st Paragraph**

Certain of the previously pending claims were rejected under 35 U.S.C. §112, 1st paragraph. In reply. Applicants respectfully traverse this rejection.

The Office Action states that the specification is enabling for a method for treating atrial tachyarrhythmia or inhibiting the onset of atrial tachyarrhythmia in a human subject comprising administering to the human subject a therapeutically effective amount of JTV-519. The Examiner states, however, that the specification “does not reasonably provide enablement for such a method of employing a genus of N-substituted derivatives of 1,4-benzothiazepine.” The claims presented herein do not recite N-substituted derivatives of 1,4-benzothiazepine, but instead recite the agent JTV-519. Accordingly, this rejection is rendered moot.

The Office Action also asserts that there is no support for the phrase “N-substituted derivative of 1,4-benzothiazepine” in the original disclosure. The claims as presented herein do not recite N-substituted derivatives of 1,4-benzothiazepine. Accordingly, this rejection is rendered moot.

In view of the amendments to the claims, Applicants request withdrawal of the rejection of the claims under 35 U.S.C. §112, 1st paragraph.

## **II. Claim Rejections Under 35 U.S.C. §103 (a)**

Claims 1, 3-6, 13, 15-18, and 25-42 were rejected under 35 U.S.C. §103 (a) as allegedly being unpatentable in view of Nakaya *et al.* In reply, Applicants respectfully traverse this rejection.

Nakaya *et al.* shows that the drug carbachol decreases the monophasic action potential duration (MAP), decreases the effective refractory period (ERP), and decreases the atrial fibrillation threshold (AFT) in isolated guinea pig hearts stimulated by artificial electrical pacing, and that the addition of 1 $\mu$ M JTV-519 reverses the decrease in MAP duration and the decrease in ERP caused by carbachol. (See page 1367 and Figure 6 of Nakaya *et al.*).

Nakaya *et al.* fails to teach or suggest a method for treating a human subject afflicted with supraventricular tachyarrhythmia, or a method for inhibiting the onset of supraventricular tachyarrhythmia in a human subject. In fact, Nakaya *et al.* fails to teach or suggest any effect of JTV-519 on supraventricular tachyarrhythmias, either in isolated guinea pig hearts or in any other experimental system or animal. Furthermore, upon reading the disclosure of Nakaya *et al.* relating to the effects of JTV-519 on MAP and ERP in isolated guinea pig hearts, one of skill in the art would not be motivated to use JTV-519 to treat supraventricular tachyarrhythmia in humans, especially given the fact that atrial fibrillation and supraventricular tachyarrhythmia are different clinical conditions. Thus, Nakaya *et al.* fails to render the present claims obvious. Accordingly, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §103 (a) is respectfully requested.

### CONCLUSION

In view of the foregoing amendments and remarks, applicants believe that all of the Examiner's concerns have been addressed. Accordingly, applicants respectfully request reconsideration and allowance of the pending claims.

Respectfully submitted,



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